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May 22, 2007

VIA HAND DELIVERY

David A. Neumann, Ph.D.,
Health Policy Analyst
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: COMAR 10.24.05 – Waivers for Hospitals to Participate in C-PORT Study of Elective Angioplasty at Hospitals without On-Site Cardiac Surgery

Dear Dr. Neumann:

Midatlantic Cardiovascular Associates, P.A. ("Midatlantic") would like to take this opportunity to express our strong opposition to the proposed elective angioplasty regulations, and to the participation in the proposed elective angioplasty study by Maryland hospitals.

Midatlantic is the largest private cardiovascular group in the central Maryland area, representing 66 cardiologists, of which 12 are interventional cardiologists. Midatlantic physicians have privileges at the following hospitals: Carroll Hospital Center, Franklin Square Hospital, Greater Baltimore Medical Center, Harford Memorial Hospital, Howard County General Hospital, Northwest Hospital Center, St. Agnes Hospital, St. Joseph Medical Center, Sinai Hospital, Union Memorial Hospital, and Upper Chesapeake Medical Center.

Midatlantic supported the original C-PORT research study in regard to *primary* PCI (acute MIs > 2 mm ST Segment elevation) and continues to support performing primary PCI for patients that present at hospitals without cardiac surgery, because of the proven clinical benefits. Currently, we provide acute services at 5 hospitals: Sinai Hospital, Union Memorial Hospital, St. Joseph Medical Center, St. Agnes Hospital and Franklin Square Hospital. While strongly committed to the benefits of acute intervention for AMIs, the group's participation was based on the scientific design in which the expected outcome was better patient care.

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Unlike primary PCI, there is no clinical benefit to be gained by performing non-primary PCI at a hospital without cardiac surgery on site. While time may be important in non-primary PCI, it is not in anyway critical. Patients may have several hours to several weeks before the intervention is performed. Patients in central Maryland are fortunate to have a choice of several excellent heart centers within a short driving distance (Johns Hopkins Hospital, Union Memorial Hospital, Sinai Hospital, University of Maryland Medical Center and St. Joseph Medical Center). These centers have shown excellent results due to significant volume coupled with experienced interventionalists and cath lab teams. These centers have enabled patients in central Maryland to have excellent clinical outcomes in the safest settings.

Since Maryland is a relatively small state (geographically), all citizens of Maryland have access to a world class Heart Center without exception…some argue, however, that the reason to allow rural hospitals without open heart surgery backup to perform elective angioplasty is to help those hospitals attract interventional cardiologists who would then be available when primary angioplasty is needed. While this argument has no relevance in metropolitan areas, the argument is also misguided in rural areas. The better solution would be to direct all patients to heart centers in the first place, as we do with the statewide trauma system.

Instead, the Health Care Commission is studying elective angioplasty to help it decide whether or not elective angioplasty should be decentralized. However, by adopting the proposed regulations, the Commission is, in fact, decentralizing elective angioplasty. Ironically, the Commission is putting the cart before the horse. Quite simply, the Commission could and should retrospectively study elective angioplasty being conducted elsewhere, without putting the people of Maryland into this "non-inferiority study" or truly decentralize and deregulate heart services by allowing cardiac surgical programs at any hospital that desires the service.

The decentralization of elective angioplasty also appears to be in conflict with the Commission's own mission. Why should the Commission be encouraging hospitals to build redundant and expensive cath labs? Why should the Commission be causing a bidding war for, and a shortage of, the highly trained staff that is necessary to run cath labs efficiently? Why should the Commission be encouraging higher relative hospital costs, since low volume centers are less efficient than high volume centers?

Furthermore, while the Research Proposal Review Committee concluded that the study is scientifically "acceptable", that conclusion was lukewarm at best, inasmuch as the Committee also set forth a number of serious reservations. Midatlantic operates an extensive research program. Our physicians have reviewed the proposed study and unanimously decided it was without true scientific merit.

Most importantly, the guidelines set forth by the American College of Cardiology/American Heart Association Task Force on Practice Guidelines with respect to PCI continue to recommend that non-primary PCI be performed only at hospitals with cardiac surgery on site. Physicians and hospitals working outside of these guidelines expose themselves

to the risk of malpractice claims if something goes wrong. For this reason, and because we believe that the C-PORT elective PCI study will put patients at unnecessary risk, please know that Midatlantic cardiologists and Midatlantic interventionalists **will not** participate in the study.

Sincerely,

MIDATLANTIC CARDIOVASCULAR ASSOCIATES, P.A.

By: Hank Yurow
Hank Yurow, Chief Executive Officer